UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

272

7590

09/09/2010

SCULLY, SCOTT, MURPHY & PRESSER, P.C. 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530 EXAMINER

BOESEN, AGNIESZKA

ART UNIT PAPER NUMBER

1648

DATE MAILED: 09/09/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,906	02/14/2007	Angeline Ingrid Bartholomeusz	19781	7415

TITLE OF INVENTION: HBV VARIANTS DETECTION AND APPLICATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	12/09/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

INSTRUCTIONS; This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where ap in m

maintenance fee notifica	ttions.	lock 1 for any change of address)	rders and notification of r a) specifying a new corres	e: A certificate of	mailing	can only be used for	domestic mailings of the
			Fee(pape have	s) Transmittal. Thi ers. Each additiona eits own certificate	is certii I paper e of mai	icate cannot be used to , such as an assignmer ling or transmission	or any other accompanying at or formal drawing, must
272		9/2010	nuv			of Mailing or Transn	
400 GARDEN O SUITE 300		I he Stat addi tran	reby certify that the	is Fee(s) Transmittal is being	deposited with the United t class mail in an envelope above, or being facsimile tte indicated below.	
GARDEN CITY	7, NY 11530						(Depositor's name)
							(Signature)
							(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR		ATTO	RNEY DOCKET NO.	CONFIRMATION NO.
10/576,906	02/14/2007	A	ngeline Ingrid Bartholome	1SZ		19781	7415
TITLE OF INVENTION	N: HBV VARIANTS DE	TECTION AND APPLIC	ATION				
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSU	E EEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO NO	\$1510	\$300	\$0	E PEE	\$1810	12/09/2010
		<u>'</u>	<u>'</u>	φ0 		\$1010	12/0//2010
EXAM		ART UNIT	CLASS-SUBCLASS				
BOESEN, A 1. Change of correspond		1648	435-005000 2. For printing on the p	atant front page. lie	n#		
CFR 1.363).		`	(1) the names of up to	3 registered paten		neys 1	
☐ Change of corresp Address form PTO/S	oondence address (or Cha B/122) attached.	inge of Correspondence	or agents OR, alternatively, (2) the name of a single firm (having as a member a 2				
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.			registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.				
3. ASSIGNEE NAME A	ND RESIDENCE DATA	A TO BE PRINTED ON	THE PATENT (print or typ	pe)			
PLEASE NOTE: Un recordation as set fort	less an assignee is ident th in 37 CFR 3.11. Com	ified below, no assignee pletion of this form is NO	data will appear on the part of the part o	atent. If an assign	ee is id	lentified below, the do	cument has been filed for
(A) NAME OF ASSI	•		(B) RESIDENCE: (CITY		COUNT	RY)	
Please check the appropr	riata assignaa catagory o	categories (will not be pr	rinted on the natent):	Individual D.C.	ornorati	on or other private gro	up entity 📮 Government
4a. The following fee(s) Issue Fee	are submitted:	41	 Payment of Fee(s): (Plea A check is enclosed. 	se first reapply ar	ny prev	iously paid issue fee s	hown above)
☐ Publication Fee (No small entity discount permitted)			☐ Payment by credit card. Form PTO-2038 is attached.				
Advance Order -	# of Copies	·	The Director is hereby overpayment, to Depo	authorized to char	ge the	required fee(s), any def (enclose an	iciency, or credit any extra copy of this form).
5. Change in Entity Sta	itus (from status indicate	d above)	overpayment, to Depo	on recount runner		(enclose an	extra copy of this form).
• •	ns SMALL ENTITY state		b. Applicant is no long				
NOTE: The Issue Fee an interest as shown by the	nd Publication Fee (if req records of the United Sta	uired) will not be accepte ites Patent and Trademark	d from anyone other than to Office.	ne applicant; a regi	istered a	attorney or agent; or the	e assignee or other party in
Authorized Signature				Date			
Typed or printed name							
This collection of inform	nation is required by 37 (FR 1 311. The information	on is required to obtain or r	etain a benefit by t	he nubl	ic which is to file (and	by the USPTO to process)
an application. Confiden submitting the complete this form and/or suggest	tiality is governed by 35 d application form to the ions for reducing this bu /irginia 22313-1450. DO	U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to th	1.14. This collection is est depending upon the indivention of the condition of the complete that the condition is considered to the complete that the condition is considered to the complete that the condition is conditional to the condition in the condition in the condition is conditional to the condition in the condition is conditional to the condition in the condition in the condition is conditional to the condition in t	imated to take 12 i idual case. Any co cr. U.S. Patent and	minutes omment Traden	to complete, including s on the amount of tin park Office, U.S. Depa	g gathering, preparing, and ne you require to complete rtment of Commerce, P.O.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,906	10/576,906 02/14/2007 Angeline Ingrid Bartholomeusz		19781	7415
272 75	90 09/09/2010	EXAMINER		
SCULLY, SCOT	T, MURPHY & PRI	BOESEN, AGNIESZKA		
400 GARDEN CIT	TY PLAZA	ART UNIT	PAPER NUMBER	
SUITE 300 GARDEN CITY, N	NY 11530		1648 DATE MAIL ED: 09/09/201	0

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 253 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 253 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 (571)-272-4200.

	Application No.	Applicant(s)
	10/576,906	BARTHOLOMEUSZ ET AL.
Notice of Allowability	Examiner	Art Unit
	AGNIESZKA BOESEN	1648
The MAILING DATE of this communication ap All claims being allowable, PROSECUTION ON THE MERITS herewith (or previously mailed), a Notice of Allowance (PTOL-8 NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT of the Office or upon petition by the applicant. See 37 CFR 1.3	IS (OR REMAINS) CLOSED in the 35) or other appropriate communi RIGHTS. This application is sub-	nis application. If not included cation will be mailed in due course. THIS
1. This communication is responsive to <u>July 9, 2010</u> .		
2. \boxtimes The allowed claim(s) is/are <u>35,37,53 and 54</u> .		
3. Acknowledgment is made of a claim for foreign priority a) All b) Some* c) None of the: 1. Certified copies of the priority documents hat 2. Certified copies of the priority documents hat 3. Copies of the certified copies of the priority of International Bureau (PCT Rule 17.2(a)). * Certified copies not received: Applicant has THREE MONTHS FROM THE "MAILING DATINOTED THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be substituted in Application of the complex of the priority of the certified copies of the priority of the priority of the certified copies of the priority of the certified copies of the priority of the certified copies of the priority of the priority of the certified copies of the priority o	ave been received. ave been received in Application documents have been received in E" of this communication to file a NMENT of this application. Domitted. Note the attached EXAM gives reason(s) why the oath or donust be submitted. erson's Patent Drawing Review (No In this national stage application from the reply complying with the requirements INER'S AMENDMENT or NOTICE OF eclaration is deficient.
Paper No./Mail Date Identifying indicia such as the application number (see 37 CFF each sheet. Replacement sheet(s) should be labeled as such i 6. DEPOSIT OF and/or INFORMATION about the de	n the header according to 37 CFR	1.121(d).
attached Examiner's comment regarding REQUIREMEN		
Attachment(s) 1. ☐ Notice of References Cited (PTO-892) 2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposition of Biological Material	6. ☐ Interview Sum Paper No./Ma 7. ☒ Examiner's Ar	rmal Patent Application nmary (PTO-413), ail Date mendment/Comment atement of Reasons for Allowance
/Agnieszka Boesen/		
Examiner, Art Unit 1648		

An examiner's amendment to the record appears below. Should the changes and/or

additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the

payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with

Steven Lendaris on September 7, 2010.

The application has been amended as follows:

IN THE CLAIMS:

Amend the allowed claims 53 and 54 as follows:

53. The method of claim 35, wherein the presence of said mutation further indicates

the resistance or reduced sensitivity to TFV.

54. The method of claim 37, wherein said HBV strain further exhibits decreased

sensitivity to TFV.

Examiners comment

It is noted that claims 35 and 37 do not refer to any specific SEQ ID NOs, however one

would know where and how to find the specific mutations recited in the claims based on the

information in Applicant's specification on page 5, lines 13-22, explaining that the amino acid

residues for HBV DNA polymerase are numbered with the residue methionine in the motif Tyr

Met Asp Asp (YMDD) being residue number 204.

Application/Control Number: 10/576,906 Page 3

Art Unit: 1648

Conclusion

Claims 35, 37, 53 and 54 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on 9:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/ Examiner, Art Unit 1648

/Zachariah Lucas/ Supervisory Patent Examiner, Art Unit 1648